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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,279	06/09/2006	Gerd Klock	31113/C720	1615

4743 7590 05/28/2008

MARSHALL, GERSTEIN & BORUN LLP
233 S. WACKER DRIVE, SUITE 6300
SEARS TOWER
CHICAGO, IL 60606

EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,279	KLOCK ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/29/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 8-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *13* is/are allowed.

6)☒ Claim(s) *1, 8-12, 14-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 29 February 2008.

Claim Status

Claims 1 and 8-16 are pending. Claims 2-7 are cancelled. Claims 1 and 8-16 are amended. Claims 1 and 8-16 are under current examination.

Oath/Declaration

The new oath or declaration, having the signatures of all inventors and executed in English, received on 1 November 2007 is in compliance with 37 CFR 1.63.

Priority

This application claims benefit from as a 371 of PCT/EP04/14097 (filed 12/10/2004). In addition, the application claims benefit from foreign application GERMANY DE 103 58 407.2 (filed 12/11/2003). The instant application has been granted the benefit date, 10 December 2004, from the application PCT/EP04/14097.

Sequence Compliance

Sequence Listing and CRF have been received and are acknowledged by examiner. A statement that the Computer Readable Form (CRF) and the Sequence Listing are identical has been submitted and is acknowledged by examiner.

The applicant has submitted amendments to the claims and specification to rectify the examiner's concerns regarding the sequence rules, requiring the use of "SEQ ID NO:" (37 CFR 1.821-1.825). As far as the examiner can determine, all aspects of the application conform to the sequence rules.

Specification

The Specification and Abstract have been amended and are now compliant with the sequence rules, requiring the use of "SEQ ID NO:" (37 CFR 1.821-1.825). Therefore, the examiner hereby withdraws the objection to the specification based on non-compliance with Sequence Rules.

The examiner thanks the applicant for pointing out the earlier amendment to the specification which added "brief description of drawings." The examiner's objection to the specification based on a lack of this section was in error and is hereby withdrawn.

All objections to the specification are withdrawn.

Response to Arguments - Claim Objections

The objections to claims 1 and 8-12 are withdrawn in response to the applicant's amendments.

Response to Arguments - Claim Rejections 35 USC § 112

Response to Arguments – 35 USC 112, second paragraph

Applicant's arguments (Remarks, page 11) and Claim amendments, filed 29 February 2008, with respect to claim 13 have been fully considered and are persuasive. The rejection of Claim 13 under 35 USC 112, second paragraph, has been made moot by the claim amendments submitted on 29 February 2008 and is hereby withdrawn.

Response to Arguments – Written Description (35 USC 112, first paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8-12, and 14-16 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments (Remarks, page 12) and claim amendments, filed 29 February 2008, with respect to claims 1, 8-12 and 14-16 rejected under 35 USC 112, 1st paragraph (written description) have been fully considered but they are unpersuasive.

The applicant has amended the instant claims so as to remove the term "functional variants." The basis of the lack of written description was directed to the genus of functional variants of nucleic acid SEQ ID NO:1. The claim amendments have made the rejection based on this particular claim language of the rejection moot. However, the applicant has introduced claim language which is essentially equivalent to the "functional variant" claim language and thus the thrust of the written description remains applicable. Newly amended claim 1 is directed to an isolated nucleic acid having a nucleic acid sequence of at least 90% sequence identity to SEQ ID NO:1 or SEQ ID NO:2 which is anti-apoptotically active.

The instant claims encompass a genus of nucleic acids having at least 90% to identity to SEQ ID NO:1-2 and having anti-apoptotic activity of at least 70%, 80%, 90% and 95% inhibition. Under the new Written Description Guidelines (March 25, 2008, Revision 1) the examiner is directed to determine whether one skilled in the art would recognize that the applicant was in possession of the claimed invention as a whole at the time of filing. The following considerations are critical to this determination:

a. Actual Reduction to Practice. In the instant case, the specification shows an embodiment, SEQ ID NO:2 (aptamer 89) which is reduced to practice.

b. Disclosure of structure. The applicant has provided sequence listings of SEQ ID NO:1 (DNA) and SEQ ID NO:2 (RNA). Additionally, with the help of a

computer, a skilled artisan could identify all nucleic acids which are at least 90% identical to the full length sequence of SEQ ID NO:1 or 2. However, neither the specification nor the art indicate a relationship between the structure of the claimed genus of nucleic acids and the recited anti-apoptotic activity. In particular, there is no indication in the art or specification as to the effect of varying up to 10% of the nucleic acids of the claimed genus of isolated on the anti-apoptotic function of the nucleic acids that are not 100% identical to SEQ ID NO:1-2.

c. Sufficient relevant identifying characteristics. As mentioned in "b" above, the complete sequence of SEQ ID NO:1-2 are provided. Furthermore, the functional characteristics of these sequences have been demonstrated in Examples 6-7 (Spec., pages 17-18). These sequences demonstrate anti-apoptotic activity. The specification indicates, "Anti-apoptotically active, in the sense of the present invention, means that the corresponding substance in the inhibition test according to Example 6, causes an inhibition index of at least 50%, preferably at least 60%, especially preferably at least 70%, even more preferably at least 80%, even more preferably still at least 90% and most preferably of all at least 95 % in relation to the control with TSP-l-induced apoptosis." (page 6, line 28 to page 7, line 2). Because of the specification's description of assays for testing anti-apoptotic activity and the specification's narrow definition of the activity being measured in Example 6, it seems that a skilled artisan would be clearly able to test a genus of polynucleotides having at least 90% identity to SEQ ID NO:1-2. However, the new written description guidelines indicate in Examples 10 and 11A that without disclosure about which nucleotides can vary from SEQ ID NO:1 or 2

and still retain the claimed activity, the examiner should conclude that the applicant was not in possession of the claimed genus of isolated nucleic acids based on disclosure of the single species of SEQ ID NO:1 or 2.

d. The method of making the claimed invention is well established.

e-f. The level of skill in the art, and the predictability in the art are all well established and/or very predictable to a skilled artisan, with regard to generating the genus of polynucleotides having at least 90% to SEQ ID NO:1 or 2. Likewise, screening such a genus would be easy for a skilled artisan. However, predicting which nucleotides can be varied from SEQ ID NO:1 or 2 and still retain anti-apoptotic activity would be unpredictable, based on the state of the art and the instant application.

Therefore, the examiner concludes that there is insufficient written description of the instantly claimed genus.

SEQ ID NO:1 and 2 are free of the art. Additionally, no prior art was found that discloses a sequence having 90% identity to the full length sequence of SEQ ID NO:1 or SEQ ID NO:2.

Therefore, the examiner hereby maintains the rejection of claims 1, 8-12, and 14-16 under 35 USC 112, 1st paragraph (written description) for the reasons of record and the comments above.

Response to Arguments - Claim Rejections 35 USC § 101

Applicant's arguments (Remarks, page 13) and Claim amendments, filed 29 February 2008, with respect to claims 1 and 8-15 have been fully considered and are persuasive. The rejection of claims 1 and 8-15 under 35 USC 101, have been made moot by the claim amendments submitted on 29 February 2008 and are hereby withdrawn.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claim 13 is allowable. Claims 1, 8-12, and 14-16 are rejected.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SDL/ Scott Long
Patent Examiner, Art Unit 1633

/Janet L. Epps-Ford/
Primary Examiner, Art Unit 1633